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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/914,046

10/01/2001

Liang Xu

2444-105-I

8537

6449

7590

01/02/2004

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EXAMINER

DIBRINO, MARIANNE NMN

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 01/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/914,046	Applicant(s) XU ET AL.	
	Examiner DiBrino Marianne	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-68 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-12, drawn to a nucleic acid cationic immunoliposome complex/pharmaceutical composition thereof comprising a *post*-linked antibody/fragment thereof, i.e., prepared wherein the nucleic acid-cationic immunoliposome complex is mixed with the antibody/fragment thereof

II. Claims 1-12, drawn to a nucleic acid cationic immunoliposome complex/pharmaceutical composition thereof comprising a *pre*-linked antibody, i.e., prepared wherein the cationic immunoliposome is mixed with the nucleic acid

III. Claims 13-25, drawn to a method of preparing a nucleic acid cationic immunoliposome complex comprising first mixing a nucleic acid with a cationic liposome and producing a complex comprising a *post*-linked antibody

IV. Claims 26-38, drawn to a method of preparing a nucleic acid cationic immunoliposome complex comprising first mixing an antibody/fragment thereof with a cationic liposome and producing complex comprising a *pre*-linked antibody, i.e., the said complex prepared wherein the cationic immunoliposome is mixed with the nucleic acid

V. Claims 39-55, drawn to a method for providing a nucleic acid cationic immunoliposome comprising a *post*-linked antibody to an animal, i.e., the said immunoliposome prepared wherein the nucleic acid-cationic immunoliposome complex is mixed with the antibody/fragment thereof

VI. Claims 39-55, drawn to a method for providing a nucleic acid cationic immunoliposome comprising a *pre*-linked antibody to an animal, i.e., prepared wherein the cationic immunoliposome is mixed with the nucleic acid

VII. Claims 56-65, drawn to a kit comprising a nucleic acid, and a cationic immunoliposome and directions for making an immunoliposome comprising a *post*-linked antibody, the said immunoliposome prepared wherein the nucleic acid-cationic immunoliposome complex is mixed with the antibody/fragment thereof

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VIII. Claims 56-65, drawn to a kit comprising a nucleic acid, and a cationic immunoliposome and directions for making an immunoliposome comprising a *pre*-linked antibody, i.e., prepared wherein the cationic immunoliposome is mixed with the nucleic acid

IX. Claims 66-68, drawn to a method of transfecting cells with a desired nucleic acid comprising administering a nucleic acid cationic immunoliposome complex comprising a *pre*-linked antibody, i.e., prepared wherein the cationic immunoliposome is mixed with the nucleic acid

X. Claims 66-68, drawn to a method of transfecting cells with a desired nucleic acid comprising administering a nucleic acid cationic immunoliposome complex comprising a *post*-linked antibody, the said immunoliposome prepared wherein the nucleic acid-cationic immunoliposome complex is mixed with the antibody/fragment thereof

3. The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Claim 1 of the instant application does not provide a technical feature that is distinguished over the prior art, as evidenced by Compagnon et al (J. Liposome Res., 7(1): 127-141, 1997, of record in the search report provided by Applicant and provided with Applicant's IDS filed August 22, 2001). Compagnon et al teach cationic liposomes complexed with antibody-polylysine conjugates, i.e., nucleic acid cationic immunoliposome complexes (see entire article, especially page 128).

Therefore, the instant invention lacks Unity of Invention.

4. **Irrespective of whichever group Applicant may elect**, Applicant is further required to (1) elect a single disclosed species of nucleic acid cationic immunoliposome as the product for Group I or Group II, or to be used in the method of one of Groups V, VI, IX or X, or to be made in the method of Group III or IV, or in the kit comprising directions to make the said immunoliposome for Groups VII or VIII (a *specific* nucleic acid cationic immunoliposome, for example, an immunoliposome comprising a post-linked antibody that binds a transferring receptor, and further comprising DNA encoding wild type p53) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

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5. If Applicant elects one of Groups V or VI, Applicant is further required to elect a specific condition such as for example, breast cancer, as the condition to be treated to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.
6. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.
7. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.
8. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).
9. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.
10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.
11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 703-308-0061 (after 1/7/04 the telephone number is 571-272-0842). The Examiner can normally be reached on Monday and Thursday.


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If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306 (before final) or 703-872-9307 (after final).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Marianne DiBrino, Ph.D.
Patent Examiner
Group 1640
Technology Center 1600
December 10, 2003



CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600